IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PAMELA BUTLER, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	No. 4:18-CV-01701-AGF
	)	Lead Case
MALLINCKRODT LLC, et al.,	)	
	)	
Defendants.	)	
	)	

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INTRODUCTION

Dr. Wells' opinions are reliable and admissible because he is qualified as an environmental geologist, and the methodologies he employs are accepted within his field. Dr. Wells has served as an expert witness in countless cases. No Court has ever struck his opinions under *Daubert*. As he has done throughout his career, he reaches his opinions by applying reliable methodologies—air dispersion equations, fate and transport evaluations, conversion calculations, and the Gore factors—to the facts and data of this case. And yet, Defendants ask this Court to be the first to exclude Dr. Wells' opinions, not by focusing on the methodologies he relies on, but by focusing primarily on legal arguments regarding the standard of care; arguments that this Court recently rejected in cases involving the same radioactive waste at issue here. Even if these arguments had any merit, they are not the proper basis for a *Daubert* ruling. Courts use their gatekeeper status under *Daubert* to exclude only those opinions that rest on scientifically invalid methodology. Dr. Wells' opinions do not fall into this category, and cannot be excluded under *Daubert*.

Beyond their standard of care arguments, Defendants take aim at certain assumptions Dr. Wells makes when applying his methodologies to the facts of the case. The Eighth Circuit is clear: an expert's factual assumptions go to the weight of his opinions, not their admissibility. As long as the expert applies sufficiently reliable methodologies, the factual assumptions underlying those methodologies must be examined by a jury. Defendants will be free to challenge Dr. Wells' assumptions, both through cross examination and presenting their own experts' testimony, but they are not entitled to have it excluded. Because Dr. Wells is qualified as an environmental geologist, and because the methodologies he employs are accepted within his field, his opinions are admissible under *Daubert*, and Defendants' motion to exclude them should be denied.

LEGAL AUTHORITY

I. Expert testimony is to be liberally admitted and only opinions that are fundamentally unsupported by scientific methodology should be excluded.

The Eight Circuit repeatedly emphasizes courts must liberally admit expert testimony and exercise their gate-keeping function to exclude only those opinions that are fundamentally unsupported by any scientific methodology. "While we adhere to this discretionary standard for review of the district court's Rule 702 gatekeeping decision, cases are legion that, correctly, under *Daubert*, call for the liberal admission of expert testimony … district courts are admonished not to weigh or assess the correctness of competing expert opinions." *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 562 (8th Cir. 2014).

Attacks directed at the factual basis of an expert's opinion generally give rise to issues of credibility, not admissibility. *Tussey v. ABB, Inc*., 746 F.3d 327, 337 (8th Cir. 2014) (additional citations omitted). "Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Osment Models, Inc. v. Mike's Train House, Inc.,* 2010 WL 4721223, at *2 quoting *Wash Solutions, Inc. v. PDQ Mfg., Inc*., 395 F.3d 888, 895 (8th Cir. 2005) (additional citations omitted). Credibility issues are properly addressed through cross-examination by the opposing party. *Id.*

II. Gaps in an expert's knowledge go to the weight of the testimony, not the admissibility.

The Eighth Circuit's requirement that expert testimony be liberally admitted extends to challenges to a witness' qualification. "[T]he relative skill or knowledge of an expert goes to the weight of that witness's testimony, not its admissibility." *Fed. Crop Ins. Corp. v. Hester,* 765 F.2d 723, 728 (8th Cir. 1985). As long as a witness has the qualifications to advance the jury's understanding of an issue *to any degree*, the witness must be allowed to testify. "Rule 702 only requires that an expert possess 'knowledge, skill, experience, training, or education' sufficient to

'assist' the trier of fact, which is 'satisfied where expert testimony advances the trier of fact's understanding to any degree.'" *Robinson v. GEICO Gen. Ins. Co.,* 447 F.3d 1096, 1100 (8th Cir. 2006) (quoting 29 FEDERAL PRACTICE AND PROCEDURE: EVIDENCE § 6265 (1997)). "Gaps in an expert witness's qualifications or knowledge generally go to the weight of the witness's testimony, not its admissibility." *Id*.

III. Disagreements with the facts assumed by an expert do not render her opinions inadmissible so long as the underlying methodologies of her opinions are reliable.

As long as an expert uses a reliable methodology, the veracity of the assumptions she makes in employing that methodology are to be addressed in cross examination. For instance, in 2007 the Eighth Circuit held plaintiff's economist was permitted to testify despite defendant's objection that "the key assumption upon which his opinion is based, essentially that the relevant market is a two supplier market, is false and ignores the existence of significant competition in the market." *Synergetics, Inc. v. Hurst,* 477 F.3d 949, 955 (8th Cir. 2007). The court held that even if this assumption were false, exclusion was not warranted because it went to the weight of the opinion:

> Vollmar's testimony was not so fundamentally unsupported that it could offer no assistance to the jury. He explained his methodology in calculating the damages, and the Appellants had the opportunity to challenge Vollmar's assumptions and methodology, both through cross-examination and by presenting their own expert witness on damages. While other methods for calculating damages may be available, so long as the methods employed are scientifically valid, *Appellants' mere disagreement with the assumptions and methodology used does not warrant exclusion of expert testimony.*

Id. (emphasis added) (citing *Daubert*, 509 U.S. at 596, 113 S.Ct. 2786 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); and *EFCO Corp. v. Symons Corp.,* 219 F.3d 734, 739 (8th Cir.2000) (no abuse of discretion to allow plaintiff's

damages expert to testify where defendant's expert, who disputed plaintiff's expert's methodology, also testified; jury left with ultimate decision as to which damages theory was more sound)).

QUALIFICATIONS

Dr. Wells is qualified to offer his opinions in this case. He holds multiple graduate degrees in Geological Sciences. Exhibit A, Expert Report, p. 2. He is a Professional Geologist (CA PG #7212), licensed by the California Board for Engineers, Land Surveyors and Geologists. *Id*. He earned his Bachelor's Degree in Earth Sciences from Dartmouth College in 1981; his Masters of Science Degree in Geological Sciences from the University of Washington in 1986; and his Ph.D. in Geological Sciences from the University of Washington in 1990. *Id.* He has more than 25 years of professional experience as an environmental geologist. *Id.* During the course of his career he has evaluated air, soil, soil vapor, and groundwater at dozens of sites around the country. *Id*. His experience includes conducting investigations to define the nature and extent of contamination in soil, air and groundwater, contaminant fate and transport modeling, allocating responsibility, and evaluating remediation strategies. *Id.*

The environmental geology community recognizes Dr. Wells as an authoritative voice in his field, qualified to evaluate the work of his peers. He is a member of the Editorial Board of Environmental Forensics, a quarterly peer-reviewed scientific journal of national and international circulation. *Id.* As a member of this Board, he evaluates the work of others through peer-review of manuscripts submitted for publication to the journal. He also participates in publication decisions, as well as establishing and maintaining the editorial direction of the journal. He is the author and coauthor of scientific publications, including forensic review articles in Environmental Science & Technology (U.K. Edition) Special Issue dedicated to Environmental Forensics. *Id.*

The State of California also recognizes Dr. Wells as an authoritative voice in his field. California's Department of Toxic Substances Control and South Coast Air Management District appointed Dr. Wells to serve as the Technical Advisor to the Exide Community Advisory Group. *Id.* In this capacity, he serves as technical liaison between community stakeholders and state regulators for this project involving evaluation and cleanup of up to 10,000 homes impacted by lead emissions from a secondary lead smelter. He shared his expertise on these matters at a legislative hearing at the state capitol in Sacramento. Like this case, the Exide Community case involved a transport mechanism of airborne emissions and dust migration in air. He is qualified to offer opinions in such cases because he is an expert in air modeling. Exhibit B, Deposition of Dr. Wells, 246:21-22. As such, he directs and oversees the employment of air modeling software such as AERMOD in the projects he undertakes. *Id.,* 246:24-248:12. When doing so, he determines not only how the particular model is to be constructed, but what input parameters should be employed, such as the mass emission rate and particle size. *Id.*

Finally, Dr. Wells has extensive experience in allocating responsibility for a contamination between parties. When he does so, he often uses the Gore factors, which are six factors that are broadly relevant to such cases and generally accepted within the field of environmental geology. *Id.,* 217:15-218:2. Dr. Wells has been employing these factors for more than 10 years.

BASES FOR OPINIONS

To arrive at his opinions, Dr. Wells reviewed thousands of pages of documents made available by the US Army Corps of Engineers (USACE), Atomic Energy Commission (AEC), and the Nuclear Regulatory Commission (NRC). Ex. A, p. 1. He also enjoyed complete access to the discovery produced by Defendants in this case. He discussed the issues in the case with James Clark, Ph.D., Plaintiffs' toxicologist, and he reviewed the report authored by Defendants' experts

for the *McClurg* cases. Ex. B, 70:7-16. He relies on reference texts commonly accepted and held reliable by experts in the fields of environmental science, hydrogeology and contaminant fate and transport, as well as the generally-accepted principles and methodologies from those fields. Ex. A., p. 1.

Dr. Wells relies on these principles and methodologies, the wealth of information made available to him, and his more than 25 years' experience in environmental science, hydrogeology, and mechanisms of contaminant migration, including groundwater, surface water and wind-borne transport, to form his opinions that both the St. Louis Airport Site ("SLAPS") and Latty Avenue were contaminated with radiological material and that this contamination escaped from these sites and impacted neighboring properties. Based on the existing data and accepted formulas, equations, and modeling, Dr. Wells is able to calculate the past offsite effluent concentrations in air, water and sediment at the boundaries of these sites. Finally, using the Gore factors, he is able to allocate the responsibility for the resulting contamination between the two Defendants.

I. The radioactive waste at SLAPS

Mallinckrodt purified uranium for the Manhattan Project in downtown St. Louis. Mallinckrodt started doing so in World War II, and continued until 1957. Ex. A, p. 5. Processing uranium, of course, creates radioactive waste, and Mallinckrodt created a great deal of radioactive waste—more than one hundred thousand tons—over the decade and a half that it operated in downtown St. Louis. Beginning in 1946, Mallinckrodt brought the radioactive waste it created to a 21.7-acre tract just north of the St. Louis Airport, now known as SLAPS. *Id.* This included pitchblende raffinate residues, radium-bearing residues, barium sulfate cake, Colorado raffinate residues, and contaminated scrap. Mallinckrodt placed some of this waste in drums, but for a

majority of the material, Mallinckrodt delivered it without containers and deposited it at the site in bulk and on open ground. *Id.,* at 5-6.

Not surprisingly, the radioactive waste Mallinckrodt created, hauled, and dumped out in the open at SLAPS did not stay put. As an example, one of the documents Dr. Wells relies on is an AEC report from 1948 entitled "Uranium Contamination at Airport Storage Area, St. Louis, Missouri." Exhibit C. The AEC identifies "mud samples" adjacent to SLAPS with uranium concentrations 190 times that of the normal uranium content in soil. *Id.,* at 4. AEC also tested surface water near SLAPS and in Coldwater Creek and found water leading into the creek contained uranium at levels reaching 7,000 ug/L, vastly exceeding the current drinking water standard of 30 ug/L. Ex. A, p. 13. Dr. Wells concludes this study shows "very significant releases of radiological contamination into surface water and stream sediments during the time waste piles were present at this site." *Id*. The AEC agrees with Dr. Wells: "[t]he results of the mud analysis showed conclusively that some residue from the area had been washed westward towards the creek." Ex. C, p. 4. Despite this report, when Mallinckrodt began operating SLAPS in 1953, it refused to collect comprehensive water samples to study the extent of the contamination coming from the radioactive waste it created and deposited at SLAPS. Ex. A, p. 13.

A. Radon

Enough data was collected at SLAPS for Dr. Wells to confirm the air concentration of radon greatly exceeded the limit of 3.0 pCi/L found in 10 CFR §20. In 1948, the AEC tested the air at SLAPS and found radon at concentrations up to 2,440 pCi/L. Ex. A, p. 14 (citing AEC, 1948, Radon Samples Taken in Airport Area, Robertson, Missouri (author: P.B. Klevin)). That same year, the AEC also measured radon concentrations at or near the fence line of SLAPS at levels up to 210 pCi/L. *Id.,* (citing RAC, 2018, Reconstruction of Plaintiff Doses Associated with Residues

Stored at the St. Louis Airport Storage Site and the Hazelwood Interim Storage Site and Critique of Opinions by Dr. Cheremisinoff, Ms. Sears and Dr. Clark, p. 5- 12). Despite this enormous presence of radon in the air from the waste Mallinckrodt created and brought to SLAPS, Mallinckrodt refused to adequately monitor the air when it began overseeing the site.

Even with Mallinckrodt's best efforts to ignore just how much of its radioactive waste was escaping into the air, Dr. Wells can confirm that the radon concentration that existed in 1948 is representative of the radon concentrations that existed during the entire time the waste Mallinckrodt created was stored at SLAPS. Based on his review of the records, the available data, and his years of experience as an environmental geologist, Dr. Wells concludes the 1948 measurements were not an outlier, and instead are representative of the air levels throughout SLAPS' entire existence. *Id.* Dr. Wells' studied the historical documents to confirm that the same radioactive waste that was responsible for the radon levels in 1948 remained at SLAPS in large quantities, stored in the same manner, until 1966. *Id.* Though some material was removed here and there, the vast majority of the radioactive waste remained. *Id.*

B. Thorium

Dr. Wells is also able to determine the concentrations of alpha-emitting radionuclides, including thorium, that were present in the air at the fence line of SLAPS during the time the radioactive waste Mallinckrodt created at its downtown plant was stored there. Ex. A, pp. 15-17. To do so, Dr. Wells starts with the measurements of uranium in the air that Mallinckrodt took in 1960. He then uses the natural abundances of the three isotopes of uranium to determine the amount of uranium-238 that was present. *Id.,* at 16. He compares this amount to the mean concentrations of different radionuclides contained in the radioactive waste Mallinckrodt created and stored at SLAPS, as calculated by Mallinckrodt's own experts. *Id*. Using this data, he is able

to model the concentration of other radionuclides in the air at the fence line including, of particular interest in this case, the excessive concentration of thorium-230. *Id*.

Dr. Wells explains that, because Mallinckrodt's measurements of uranium underrepresent the yearly average, so too does his calculation of the excessive concentration of thorium-230 at the fence line. *Id.,* 16-17. These values underrepresent the yearly average because they do not account for high wind events. Over the course of a year, the vast majority of dust generation occurs only during those days or portions of a day with high winds. *Id*. On most days, the wind is mild and will create little dust. *Id*. Mallinckrodt made no effort to collect air samples on windy days and, as a result, Mallinckrodt's sampling underestimates "average" airborne concentrations. Hence, Dr. Wells' calculations showing an excessive amount of thorium-230 at the fence line underestimate the true yearly average of thorium in the air.

II. The radioactive waste at Latty Avenue.

A. Radon

Dr. Wells calculates the radon concentration at the Latty Avenue fence line by using the well-established formula DF = χ/Q. In this formula, DF = Dispersion Factor; χ = Concentration in air at a given point; and Q = release rate. Ex. A pp. 14-15. He finds the values for each of these in a report conducted by Defendants' experts. *Id.* Risk Assessment Corporation reports a release rate of 1.2 x 10-4 Ci/s (RAC, 2018, p. 4-35); a perimeter dispersion factor of 6.21 x 10-5 s/m3 (RAC, 2018, p. 4-32); and an average radon concentration measured at SLAPS of 168 pCi/L (RAC, 2018, p. 4-35). *Id.* Using these values, Dr. Wells calculates the radon concentration at the fence line at Latty Avenue to be 7,450 pCi/m3, or 7.45 pCi/L. In his opinion, and for the same reasons discussed above for SLAPS, this concentration is representative of the entire period of time that the waste

material was stored at Latty Avenue, without accounting for high wind events, and therefore underreports the true yearly average. *Id.*

Again, like SLAPS, Dr. Wells reviews the material stored at Latty Avenue, compares it to what was stored at SLAPS, and recognizes that the vast majority of the radioactive waste at SLAPS (with a few exceptions, such as the K-65 and possibly the drums it was stored in) was moved to Latty Avenue and stored in the same manner there—out in the open with no environmental precautions. Ex. B, 331:8-333:21. To verify the assumptions he makes when calculating radon levels at Latty Avenue, Dr. Wells reviewed the measurements taken at Latty Avenue well after most of the material was removed, finding that the concentrations in the air continue to be high. Ex. A, p. 15. For example, in the 1990s, radon concentrations at the Latty Avenue fence line were up to approximately 0.6 pCi/L and in 2015, SLAPS outdoor radon concentrations were up to 0.4 pCi/L. *Id.* That the radon levels remained so far above background decades after the waste piles were removed confirms they were much higher during the time the piles were actually present at Latty Avenue, just as Dr. Wells calculated.

B. Thorium

Dr. Wells also calculates the concentration of radioactive particulates in the air at the boundaries of Latty Avenue. As with much of his other opinions, he begins with measurements taken, and data generated, by Mallinckrodt and its experts. *Id.,* at 17. It is undisputed that the drying operation at Latty Avenue pumped an enormous amount of radioactive dust into the air—Defendants' own experts put the total amount at over 10 tons. *Id.* These experts also calculate the total curies each radionuclide produced during this operation. *Id*. It is this information that Dr. Wells relies on to calculate the concentrations of these radionuclides in the air in and around Latty Avenue, by dividing them by the total amount of volume of air passing across the site. *Id.*

As he does for radon at Latty Avenue, Dr. Wells tests his results by comparing them with the other information known about the site. He explains his results are consistent with the AEC's finding of excessive radiation at Latty Avenue: "radiation levels were found emitting from the stockpile area in excess of 1.3 mr/hr at 1 meter from the ground and from the barrel storage area at 10 mr/hr at 18 inches from the barrels. Therefore, contrary to 10 CFR 20.105(b)(2), radiation levels exist in the stockpile area and unrestricted area, such that an individual continuously present in this area could receive a dose in excess of 100 millirem in any seven days." *Id.* (citing AEC, Inspection Sheet for January 11, 1967 Inspection) (emphasis added by Dr. Wells.). The AEC found levels above what is acceptable, and so does Dr. Wells.

III. Solubility of thorium-230.

In his opinions, Dr. Wells refers to limitations contained in 10 CFR §20. This section includes different limits for "soluble" and "insoluble" forms of each radionuclide. Because the regulations do not provide a definition for these terms, Dr. Wells studies the record to determine which term best describes the radionuclides at issue in this case. Ex. A, p. 12. First, he relies on the original source of these effluent limitations, a 1959 Commerce Department publication entitled, "Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air and in Water for Occupational Exposure." *Id.* In this document, Dr. Wells concludes the terms "soluble" and "insoluble" refer to the behavior of substances in the body, a concept that is now referred to as "bioavailability." *Id.* In other words, the question is not how soluble these substances are in water, but whether or not they are soluble inside the human body, such as in stomach acid, for example. Ex. B, 207:16-208:2. And as Dr. Wells observes, the Department of Energy (DOE) agrees that these substances are best defined as "soluble" for purposes of regulation. In its 1979 radiological survey of the SLAPS site, DOE classified these

substances as "soluble" and uses the effluent limitations for soluble radionuclides. Ex. A, p. 12. Based on all of this, Dr. Wells concludes that these materials are "soluble" in the environmental science sense and, therefore, as that term is used in 10 CFR §20.

IV. Allocation.

Dr. Wells, pursuant to an order from this Court that Plaintiffs' experts attribute the specific amount of exposure to Cotter and Mallinckrodt, allocated responsibility for the contamination between these two defendants. Ex. A, pp. 19-22. This is not the first contamination case Dr. wells has offered allocation opinions. When he does so, he uses the Gore factors, which are six factors that are "broadly relevant in cases where one is trying to conduct some type of allocation of contamination." Ex. B, 216:4-6. These factors are used "whenever there's a dispute about multiple responsible parties having to divvy up cleanup responsibilities or -- or some other consequences of contamination." Ex. B, 217:22-25. Applying these factors to this case, and paying particular attention to the total years the materials were stored at SLAPS and Latty Avenue, Dr. Wells was able to allocate responsibility between these two Defendants for the contamination of four different sites, over three different time periods. Ex. A, p. 22.

V. Supplemental Report

Finally, Dr. Wells issued a supplemental report to help give further context to his opinions. Exhibit D, Supplemental Report. In this report, he identifies and describes Cotter's actions that violated the standard of care for the hazardous materials. He discusses how these actions directly led to the excessive effluent levels he addresses in his original report. And lastly, he explains how the Defendants' possession, use and/or transfer of wastes at both SLAPS and Latty Avenue caused excessive radiation to be released in the form of contaminated sediments into Coldwater Creek.

ARGUMENT

I. In Missouri, Mallinckrodt is strictly liable for handling and processing nuclear material, including creating and delivering radioactive waste.

Mallinckrodt asks the Court to strike Dr. Wells' opinions regarding pre-1953 contamination, not because of some flaw in his methodology, but because Mallinckrodt enjoys complete immunity for its actions until it began operating SLAPS in 1953. How this can be, given that Mallinckrodt is strictly liable for creating, hauling, and disposing of radioactive waste at SLAPS, Mallinckrodt does not say. Nor does it provide any authority in support.

As this Court holds, strict liability applies to the claims against Mallinckrodt for all pre-1957 releases:

> The Court also agrees with Plaintiffs, and Mallinckrodt does not dispute, that under Missouri tort law, injuries arising from Mallinckrodt's handling of radioactive materials would be subject to strict liability. *See Bennett v. Mallinckrodt, Inc.,* 698 S.W.2d 854, 870 (Mo. Ct. App. 1985) ("Strict liability is an appropriate principle for activities generating radioactive emissions.").
>
> As such, Mallinckrodt may be held strictly liable under the PAA for its pre-1957 releases, and by the same token, Plaintiffs may state a PAA public liability action against Mallinckrodt without pleading a breach of any specific dose limit.

Doc 262, p. 17-18.

Despite this, Mallinckrodt asks the Court to ignore its previous holding and the well-established law in Missouri and grant it immunity for purifying uranium, creating radioactive waste, handling that radioactive waste, and delivering that radioactive waste to SLAPS in unprotected and uncontained piles, where it continued to release radiation into the environment. Mallinckrodt cites no legal authority for such immunity, and none exists. Nor is Mallinckrodt's prayer for such immunity appropriate relief in a *Daubert* motion. At issue is the reliability of Dr. Wells' methodology and opinions, not the legal merits of Mallinckrodt's unconventional defense.

II. 10 CFR §20 does not govern the standard of care because Mallinckrodt was not licensed, nor was the radioactive waste it created and delivered to SLAPS.

Again, rather than criticizing the scientific methodology Dr. Wells employs to calculate the level of effluents in the air, Mallinckrodt seeks to exclude his opinions by arguing the standard of care. This time, Mallinckrodt claims that the concentration of radionuclides in the air at the fence line are irrelevant unless averaged over a full year. Mallinckrodt insists this is the case despite the plain language of 10 C.F.R. §20.106(a) that "concentrations *may* be averaged over a period not greater than one year." (emphasis added) In support of its request to have the Court reinterpret "may" to mean "shall," Mallinckrodt relies on a single case, *McMunn v. Babcock & Wilcox Power Gen. Grp.,* 869 F.3d 246 (3d Cir. 2017).

In *McMunn*, the court acknowledged the use of the word "may" in section 20.106 is permissive, not mandatory. *McMunn*, 869 F.3d at 266. Nonetheless, the court held that because §20.106 sets forth duties of licensees enforced by the AEC, the AEC holds the discretion to average concentrations over a year, not a plaintiff: "Given the context of the regulation, the obvious answer is that such discretion lies in the AEC because it is the entity charged with determining whether a licensee violates its regulatory duties." *Id.* But unlike the defendant in *McMunn*, Mallinckrodt is not a licensee. Ex. L, October 31, 2016 deposition of Mallinckrodt corporate representative, Roy Brown, p. 88:7-10; 88:22-24. And from the time Mallinckrodt created the radioactive waste up through the time it operated SLAPS, no license existed. *Id.*

The plain language of §§20.105 and 20.106 confirms they do not apply to non-licensees. Section 20.106 requires that "no *licensee* shall possess, use or transfer licensed material in such a manner as to release into air or water\in any unrestricted area any concentration of radioactive material in excess of the limits specified in Appendix B, Table II, of this part." Exhibit E, 25 Fed. Reg. 8599 (1960) (used as Ex. 11 to the deposition of Dr. Wells) (emphasis added). Likewise,

§20.105 provides "no *licensee* shall possess, use or transfer licensed material in such a manner…" *Id*., at 8598 (emphasis added). The Third Circuit also recognizes these sections govern the behavior of licensees: "The AEC concluded the new regulations represented 'an appropriate regulatory basis for protection of the health and safety of employees and the public *without imposing undue burdens upon licensed users of radioactive material*.'" *In re TMI*, 67 F.3d 1103, 1111 (3d Cir. 1995) (quoting 25 Fed.Reg. 8595, 8595 (1960)) (emphasis added).

Because no license existed relating to Mallinckrodt, these sections do not apply to Mallinckrodt's conduct in this case. "Although it is well established that a federally defined standard of care must replace any state standard in a PAA public liability action, the principle holds true only to the extent an applicable federal standard of care exists." Doc. 262, p. 17. No applicable federal standard of care exists for Mallinckrodt; it is strictly liable.

Even if Mallinckrodt had obtained a license, there would still be no applicable federal standard of care. The material at issue in this case, waste materials Mallinckrodt generated while extracting uranium, was not regulated by the federal government until 1978. In 1990, the Circuit Court of the District of Columbia held that before 1978 "The AEA made no provision for regulating waste materials generated during the extraction or concentration of source material." *Kerr-McGee Chem. Corp. v. U.S. Nuclear Regul. Comm'n*., 903 F.2d 1, 2 (D.C. Cir. 1990). As the court explained, even though by "the 1960's and early 1970's, federal and state authorities began to realize that wastes, or 'mill tailings,' resulting from the extraction or concentration of source material posed a significant public health problem," these waste materials "lay outside the AEC's statutory licensing authority and therefore beyond its regulatory reach." *Kerr-McGee*, 903 at 3.

This Court follows the precedence set by the D.C. Circuit in *Kerr-McGee* and holds that no applicable federal standard of care existed for the material at issue in this case until 1978. "It

was not until 1978 that Congress expanded the definition of 'byproduct material' to include uranium and thorium mill tailings. 42 U.S.C. § 2014(e)(2)." *Strong v. Republic Servs., Inc.,* 283 F. Supp. 3d 759, 772-73 (E.D. Mo. 2017). *See also Banks v. Cotter Corp*., No. 4:18-CV-00624 JAR, 2019 WL 1426259, at *8 (E.D. Mo. Mar. 29, 2019) ("Moreover, the Uranium Mill Tailing Radiation Control Act of 1978 ('UMTRCA'), which first included uranium mill tailings in the definition of byproduct material, states that the amendments 'shall take effect on the date of the enactment of the Act.' PL 95–604 (HR 13650), Nov. 8, 1978, 92 Stat. 3021, Title II - Uranium Mill Tailings Licensing and Regulation Definition, Sec. 208.").

The Court should not ignore this precedence, as Mallinckrodt does. The Third Circuit cases Mallinckrodt relies on, *McMunn* and *In re TMI*, are off-point; they do not address the material at issue in this case. Mallinckrodt was an unlicensed entity, working with unlicensed material, years before the Atomic Energy Act was amended in 1978 to cover such material. Likewise, Cotter's conduct in this case occurred entirely before 1978. There is no applicable federal standard of care governing either Defendant in this case. This is a strict liability case.

III. Because Dr. Wells' offers opinions of the air concentration at the fence line during the entire period that the piles of radioactive waste Mallinckrodt created were present, his opinions satisfy the standard Mallinckrodt asks the Court to adopt.

Even if the Court holds §§20.105 and 20.106 apply to this material and these Defendants, and even if the Court accepts Mallinckrodt's argument that Plaintiffs must prove excessive releases when averaged over an entire year, Dr. Wells' opinions still satisfy this standard. He applies reliable methodologies to the available data to calculate the average air concentrations at SLAPS and Latty Avenue. The data he relies on is from measurements taken by Mallinckrodt during its annual monitoring program. As explained above, based on his review of the historical record and his examination of the fate of the waste materials Mallinckrodt created and delivered to SLAPS,

he concludes the calculations he derives from these measurements are not just reliable for the day they were measured, but also a "reliable example of air concentrations at the fence line of the SLAPS site during the period of time that waste piles were present." Ex. A, p. 16. As he explains, given that Mallinckrodt did not account for wind events, which will raise the yearly average, when taking measurements, his calculations on air concentration are well below the true average for any given year that the material was stored at SLAPS (1946-1966). *Id.* At 16-17.

Mallinckrodt's criticism that he focuses on the highest results to the exclusion of other results are off-base and misleading. Mallinckrodt attacks Dr. Wells by claiming there are twelve measurements, not one, and therefore Dr. Wells' opinion must be excluded for failing to use the "annual average listed in the report." Mallinckrodt's Brief, p. 11. This is a misrepresentation—the report does not list an "annual average" from a single location. Exhibit F, Data Capture Document Discovery (used as Exhibit 10 to Dr. Wells' deposition). Instead, it lists the "average" of test results from *multiple* locations. *Id.,* at 10. Contrary to Mallinckrodt's assertion, nothing in "the language of §20.106, *McMunn*, or established radiation safety" requires Dr. Wells to average measurements from different locations. Mallinckrodt's Brief, p. 11. To the extent §20.106 applies, it prohibits Mallinckrodt from exceeding the limits at any one location in an unrestricted area. In other words, Mallinckrodt cannot escape liability for causing excessive concentrations at Location A by pointing to Location B, which has far less concentrations, and demanding the two locations be averaged together.

And yet that is exactly what Mallinckrodt asks the Court to do. It is clear from the face of the report Dr. Wells relies on that there are six different test locations. Ex. E, p. 10. The "sampling frequency" is "semiannually," and there is a total of 12 samples: Two each from East, West, and South of the site, and six from North of the site. *Id.* Hence, there are a minimum of six different

sample locations: one each from the East, West, and South; and at least three (and possibly up to six) from the North. Mallinckrodt faults Dr. Wells for not averaging all six of the samples from North of the site together. But it would make no sense for him to do so. Mallinckrodt breaches the limitations of section 20.106 if it exceeds those limits at any single location North of the site. Averaging the "good" locations with the "bad" locations, simply because they are all North of the site, wrongly allows Mallinckrodt to escape liability for exceeding the limits at the bad locations. Nothing in the regulations permits such a result. Dr. Wells was correct to treat each sample location separately. His opinions are admissible even if the Court finds §§20.105 and 20.106 apply.

IV. Dr. Wells appropriately accounted for the removal of the K-65 waste.

Dr. Wells appropriately accounted for the removal of K-65. K-65 waste certainly produced some radon, but the idea that the K-65 drums constituted a lion's share of the radon released at SLAPS is an opinion Defendants' experts formed for purposes of this litigation. Volumetrically, this waste was a very small part of the overall waste inventory at SLAPS. RAC (2018) summarized the mass of various waste types stored at SLAPS as of 1965 and concluded that K-65 waste accounted for approximately 1.3% of the total stored at SLAPS (1,757 tons of K-65; 133,957 tons of total waste; 1,757/133957=0.013). Exhibit G, pp. 4-7, 4-8. And unlike the vast majority of SLAPS waste, K-65 material was stored in sealed drums, greatly reducing the ability of radon to escape to the atmosphere. Ex. B, 182:9-18. These sealed drums were responsible for only a small part of overall radon emissions compared to other wastes comprising vastly greater volumes that were completely uncontained and that remained at SLAPS for much longer periods of time. In addition, the empty K-65 drums were returned to SLAPS where K-65 residues in the empty (and presumably open) drums would have continued to emit radon.

Dr. Wells relies on a fence line measurement from SLAPS that was taken almost 200 feet from the drum storage area that shows a radon concentration of 210 pCi/L. Meanwhile, a measurement taken from the same area but only 150 feet from the drum storage area revealed a radon concentration of 89 pCi/L; and one taken even closer, at 100 feet, showed a radon concentration of 49 pCi/L. Exhibit M, pp. 3 and 5 (highlights added). The K-65 in these drums was not skewing the radon levels Dr. Wells relied on upwards. Instead, *the closer the measurements got to the drum storage area, the lower the radon results became*. These results prove the K-65 wastes were not the major source, let alone the sole source Defendants suggest, of radon at SLAPS. In fact, Mallinckrodt's own expert, Dr. Till, documented that there was significant radon flux from the uncontained waste piles of AJ-4, AM-7 and AM-10. Ex. F, Table 4-18. He found radon measurements in excess of 100 pCi/L atop the AM-7 waste pile, which was 0.15 km—nearly 500 feet—from the drum storage area. Exhibit O, Figure 5-4 (arrow added).

Based on all of this, and as Dr. Wells explains in his deposition, the removal of the K-65 drums from SLAPS do not invalidate his opinions of the radiation levels at the fence line:

> Q The removal of the K-65 from SLAPS would have reduced the production of radon at SLAPS, correct?
>
> A It would have reduced the production of radon at SLAPS. It wouldn't necessarily have reduced the concentrations in air at the fence line.
>
> Q Why is that?
>
> A Well, because all the other waste materials were -- were still there, and this -- I mean, sure, there would be some possibly unmeasurable change, but the other waste materials, which occupied a much larger area and also were uncontained, also were producing radon-222.

Ex. B, 176:14-177:3.

Dr. Wells applied proper and reliable methodologies to reach his conclusion that the removal of K-65 had an insignificant impact on the radon level at SLAPS. He explained these

methodologies and his reasoning at his deposition. To the extent Defendants disagree with his conclusion that the removal of K-65 did not significantly change the radon levels, their disagreement is a matter for cross examination, not exclusion. The same is true regarding Cotter's complaint that Dr. Wells used the radon level at SLAPS as a proxy for Latty Avenue.[1] Dr. Wells explains the K-65 was not a significant contributor to radon levels and other than that essentially the same material was stored in a similar manner at Latty Avenue as it had been at SLAPS. A party's "mere disagreement with the assumptions and methodology used does not warrant exclusion of expert testimony." *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 955 (8th Cir. 2007).

In *Synergetics,* plaintiff's economist was permitted to testify despite the fact that his opinions rested entirely on the assumption that the market was only a two-supplier market, something the defendants insisted there was no evidence of. The Eighth Circuit held whether or not this assumption was appropriate could only be determined by a jury. *Id.* This was so because the expert "explained his methodology," which was "scientifically valid," and the defendant could challenge his assumptions underlying the methodology "both through cross-examination and by presenting their own expert witness." *Id.*

Here, there is no doubt Dr. Wells' methodologies—interpretations of historical measurements, as well as air dispersion formulas and models—are scientifically valid. Nor is there any doubt that he explains these methodologies in his report and deposition. Hence, just as in *Synergetics*, Defendants' disagreements with the assumptions he makes, such as the assumption that the presence of the K-65 did not significantly affect radon levels, goes to the weight, not admissibility of his opinions. The jury can find in Plaintiffs' favor on this disputed issue of fact,

[1]Cotter's claims that Dr. Wells' assumptions led to him overestimating the concentration by 173 times is without merit. According to its expert, Dr. Wells would have calculated a concentration was 0.043 pCi/L, which is an absurd 13 times lower than the 0.6 pCi/L levels that remained at the fence line two decades later. *See* Cotter's Ex. A, p. 29.

and this assumption does not render Dr. Wells' opinions "so fundamentally unsupported that it could offer no assistance to the jury." *Id.*

V. Because the thorium at issue is biologically soluble, Dr. Wells was correct to treat it as soluble under 10 CFR § 20, should the Court find that sections applies.

As discussed above, based on his review of the 1959 Commerce Department publication entitled, "Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air and in Water for Occupational Exposure," his familiarity with the literature regarding "bioavailability," and the DOE's own classification of the material at issue in this case as soluble, Dr. Wells concludes the radionuclides at issue in this case, particularly thorium, were soluble. Mallinckrodt disagrees, and asks the Court to exclude his opinions for failing to classify the thorium in this case as insoluble.

Mallinckrodt attempts to muddy the waters by conflating the common or lay usage of "soluble," used to describe things that dissolve completely in water (such as salt or sugar), with how that term is used when discussing matters of environmental science. In environmental science, "soluble" is used to describe a solid compound that is *soluble enough* to cause toxic or otherwise problematic concentrations, whether in water or inside the body. Even sparingly soluble solids can dissolve enough to cause toxic levels in fluids if they are toxic enough. Considering the extreme toxicity of some of the radionuclides in this case, it is appropriate to categorize them as soluble.

Mallinckrodt argues that the DOE's classification of the thorium in this case as soluble cannot support Dr. Wells' opinion because the DOE only classified it as soluble "because it was a lower value, not because the DOE determined the solubility of the thorium." Mallinckrodt's Brief, p. 14. Even Cotter's expert does not buy this argument. In his report for Cotter in this case, Malcom R. Knapp, Ph.D. admits that the DOE classified thorium as soluble, not merely because it was a lower value, but because the DOE was actually observing soluble thorium: "As seen in the DOE

report, DOE was reporting radionuclide concentrations in water samples from Coldwater Creek and drainage ditches. Obviously, if thorium dissolved in water is to be compared to Part 20 limits, the appropriate limit is for soluble thorium." Exhibit H, p. 32.

The DOE is not the only entity to observe that the thorium at the site is soluble. Repeated testing of surface water and groundwater at the site show radioactive compounds are found dissolved in water. Researchers from Argonne National Laboratory reported up to 8,700 pCi/L of total uranium; up to 4.0 pCi/L of 226Ra and up to 130 pCi/L of 230Th in groundwater under SLAPS Ex. N, Argonne National Laboratory, November 1993, Baseline Risk Assessment for Exposure to Contaminants at the St. Louis Site, St. Louis, Missouri, Table 2.5. If Mallinckrodt's is correct that these compounds were insoluble, then they would not be found dissolved in water in and around the site. In fact, there is no evidence that any workers at the site, or regulatory entities, have ever classified the SLAPS wastes as "insoluble."

And Mallinckrodt offers no expert who independently concludes otherwise. Instead, Mallinckrodt relies on an unsigned 1986 letter purporting to have been written by Dr. Dick Duffey. Exhibit I. This is the only evidence Mallinckrodt provides of the chemical form thorium existed in at SLAPS and Latty Avenue. In this letter, Dr. Duffey purports to speculate as to what "probably" or "presumably" happened to the thorium as Mallinckrodt purified the uranium. *Id.* This unpublished, unsigned letter lacks any foundation and is inadmissible. It certainly cannot serve as the basis for the Court to conclude that, as a matter of law, the thorium at issue in this case is insoluble. Especially when Drs. Wells and Knapp, the DOE, and every other entity to actually observe the thorium at these sites disagrees. Dr. Wells' opinion that the radionuclides are best classified as soluble is based on solid methodology, supported by the evidence, and admissible.

VI. Dr. Wells' "box model" is a reliable, accepted, and commonly used methodology.

In environmental science, the distinction is often made between screening models and full scale (often 3-D) numerical models. Complex models of environmental processes require very large amounts of input data. Thus, these models are only useful if sufficient input data are available. Otherwise, such models may give the appearance of accuracy and reliability, but they will not be good simulations of actual processes in the real world. As the EPA explains: "…it is also true that in many field situations few data are available; hence, complex numerical models are often of limited use." Ex. K, EPA, 1992, Fundamentals of Groundwater Modeling, p. 7.

Because of this, it is a generally accepted practice to begin with a simple ("screening") model and then decide if a more complex model will be reliable enough to be useful. "The exposure assessor or risk manager can then determine whether the results of the screening-level assessment warrant further evaluation through refinements of the input data and exposure assumptions or by using more advanced models." Ex. J, "Exposure Assessment Tools by Tiers and Types—Screening Level and Refined," accessed 9/2/2021). *See also* U.S. EPA, A Tiered Modeling Approach for Assessing the Risks Due to Sources of Hazardous Air Pollutants, 1992. And even Cotter's experts agree a screening model is appropriate; they used the "AERSCREEN," itself a screening model.

There is nothing that renders Dr. Wells' choice to employ the screening model he did, a "box model," as invalid. It is a widely employed model formulation, commonly used to study a large variety of environmental problems, and that frequently appears in studies published in peer-reviewed scientific literature.[2] The box model Dr. Wells employs is a reliable methodology.

[2]Four examples are: Jin and Demerjian, 1993, A photochemical box model for urban air quality study, Atmospheric Environment, v. 27B, pp. 371-387; 3. Schenker, et al., 2007, Including degradation products of persistent organic pollutants in a global multi-media box model, Environmental Science and Pollution Research, v. 14, pp. 145-152; Zhou, et al., 2020, Estimating the remaining atmospheric environmental capacity using a single-box model in a high pollution risk suburb of Chengdu, China, Journal of Environmental Management, v. 258, pp. 110052-57; and 7.

VII. Because he uses methods generally relied on by experts in his field, Dr. Wells' allocation opinions are admissible and will assist the jury in allocating fault.

Dr. Wells applies the Gore factors to allocate responsibility for the contamination between Defendants. He explains these factors, including which one is most relevant here and that they do not involve a precise calculation because such a calculation is impossible. Mallinckrodt faults Dr. Wells for failing to precisely calculate exposure levels for each Defendant, but the Eighth Circuit does not require "a mathematically precise table equating levels of exposure with levels of harm." *Bonner v. ISP Tech*, 259 F.3d 924 at 928 (8th Cir. 2001). The same is true for allocating fault between defendants. Rather, an opinions s still admissible where, as Dr. Clark does, the expert "explains why such an estimate is not possible." *Kirk v. Schaeffler Group USA, Inc*., 887 F.3d 376, 391 (8th Cir. 2018).

Dr. Wells explains why a precise calculation of allocation is impossible, and applies the generally accepted Gore factors to arrive at his opinion on the estimated allocation. He is an expert at allocating responsibility between parties for a contamination and his expertise will undoubtedly be helpful to the jury as it allocates fault in this case. His allocation opinions are admissible.

VIII. Mallinckrodt has long waived its argument that Dr. Wells' opinions do not comply with this Court's October 15, 2018 Order.

On October 15, 2018, this Court entered its Case Management Order No. 14 which, among other things, requires all Plaintiffs to serve case-specific expert reports within 60 days of filing. Doc. 741, p. 9. The Court did so because it felt it appropriate "to require future Plaintiffs to make a threshold showing on key elements of their claims at the outset of the litigation." *Id,* at 1. Among the requirement of the expert reports was to quantify the doses of radiation Plaintiffs were exposed

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Peterson, et al., 2007, A box model to quantify groundwater discharge along the Kona coast of Hawaii using natural tracers, in: A New Focus on Groundwater-Seawater Interactions (Proceedings of Sumposium HS1001 at IUGG2007), IAHS Publication 312.

to that were attributable to each Defendant. The Court gave Defendants a procedure to address any deficiencies in these reports should they find them inadequate, including giving notice of the deficiency via email or fax and a requirement to meet and confer following Plaintiffs' failure to cure the deficiency. *Id.,* at 11.

Despite this, Defendants never complained that the reports did not comply with the Court's requirements until now. Defendants have long since waived the opportunity to do so. Dr. Wells' allocation opinions will assist the jury in apportioning fault. It is far too late, and violates the Court's October 2018 order, for Defendants to now insist that, notwithstanding the scientific basis for Dr. Wells' allocation, Plaintiffs need to present a different report on allocation to comply.

CONCLUSION

Dr. Wells is qualified to opine on the fate of environmental toxins, which is what he has done in this case. He does not need a degree or certification in radioactive isotopes to offer his opinions in this case anymore than he needs a degree or certification in lead to offer the opinions he has in cases involving lead. He applies the facts and data to reliable methodologies generally accepted by the environmental geology community. As such, his opinions on contamination levels and allocation are reliable and admissible under *Daubert*. And, because they will help the jury determine the issues in these cases, his opinions are relevant under the law. No grounds exist to exclude his testimony. Mallinckrodt's motion, and Cotter's joinder and supplemental memorandum, should be denied.

Respectfully Submitted,

HUMPHREY, FARRINGTON & McCLAIN, P.C.

/s/ Jonathan Soper
Kenneth B. McClain #32430
Jonathan M. Soper #61204
Colin W. McClain #64012
221 West Lexington, Suite 400
Independence, MO 64050
Telephone: (816) 836-5050
Facsimile: (816) 836-8966
kbm@hfmlegal.com
jms@hfmlegal.com
cwm@hfmlegal.com
ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on the 29th day of September, 2021, I electronically filed the above with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to counsel of record.

/s/ Jonathan Soper
Attorney for Plaintiffs

SHOOK, HARDY & BACON LLP
David R. Erickson # 31532MO
Steven D. Soden # 41917MO
Anthony R. Martinez # 61791MO
2555 Grand Boulevard
Kansas City, MO 64108-2613
Phone: (816) 474-6550
Fax: (816) 421-5547
derickson@shb.com
ssoden@shb.com
amartinez@shb.com
ATTORNEYS FOR DEFENDANT MALLINCKRODT LLC

RILEY SAFER HOLMES & CANCILA, LLP
Brian O. Watson, #68678MO
70 W. Madison St., Ste. 2900
Chicago, Illinois 60602
Telephone: (312) 471-8700
Facsimile: (816) 836-8966
bwatson@rshc-law.com
ATTORNEY FOR DEFENDANT COTTER CORPORATION (N.S.L)